

BARNES & THORNBURG LLP

600 One Summit Square
Fort Wayne, Indiana 46802
(260) 423-9440

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Customer No.: 23641
Application No.: 10/607227
Confirmation
No.: 5896
Filing Date: June 26, 2003
Attorney
Docket No.: 50460/83518
First Named
Inventor: William E. Spindler
Group Art
Unit: 1711
Examiner
Name: Bibi Sharidan Carrillo
Title: CLEANING COMPOUND FOR
CLEANING SURFACES IN A FOOD
PROCESSING ENVIROMENT

I hereby certify that this correspondence
is being electronically filed with the
Commissioner for Patents

on: April 22, 2010

/Gregory S. Cooper/
Gregory S. Cooper

DECLARATION PURSUANT TO 37 C.F.R. § 1.132

Sir or Madam:

I declare as follows:

1. I, William E. Spindler, am over 18 years of age and am President of Wayne Chemical Inc., of Fort Wayne, Indiana, a company that I founded in 1969. I earned a Bachelor of Arts degree with a major in chemistry from the University of St. Francis in 1965 after attending Indiana University for three years. Over the course of my career, I have created

several hundred chemical products, approximately 75 types of chemical application equipment for the food processing industry, and have been listed as an inventor on several U.S. patents.

2. I am a named inventor on this application in addition to being owner of the assignee.

3. I have read the Office Action dated October 22, 2009, and cited art. As a result, there are a few issues which I believe need to be cleared up.

4. *Listeria* or *listeria monocytogenes* is a bacteria that can cause listeriosis, a potentially lethal food-borne infection. In the United States, *listeria* contaminates the food supply often at the point of manufacture. It is for reasons like this food manufacturing plants have very stringent cleaning and sanitation requirements.

5. Cleansing a food processing plant requires generally, two steps. (See 9 CFR 416, §416.4, 4-603.14 Wet Cleaning and 4-702.11 Before Use After Cleaning.) After a mechanical pickup and a water rinse, cleaner is applied followed by a rinse of sanitizer. This procedure is required by USDA and FDA and sanitizers are controlled by EPA. Sanitizer labels, which are required by the EPA, state that if a surface is soiled, the surface must be cleaned before the sanitizer is applied.

6. Before the subject matter of this patent application was developed, all food plants were first cleaned with chlorinated cleaners and then sanitized using either iodophores, bleach (sodium hypochloride) or quaternary ammonium sanitizers.

7. Despite the wide spread use of chlorinated cleaning products they 1) promote corrosion which can cause significant damage to the food processing plant over time; 2) damage the environment when in the plant's effluent; and 3) fail to clean as well as the subject matter of the present application. In fact, when *listeria* contamination breaks out in a food processing plant that cleans with chlorinated cleaners per government standards, it is the subject matter of this patent application that cleans the plant to an extent that chlorinated cleaners can't.

8. For example, on or about 5/22/09, Wayne Chemical Inc. was contacted by United Food Group, LLC. United Food Group's primary business is grinding red meats. They informed us that the USDA had shut them down for *Listeria monocytogenes* contamination and recalled ground meat. United Food Group had heard about Wayne Chemical Inc.'s products from their consultants. Prior to the recall, United Food Group was utilizing a chlorinated cleaner to clean their plant. They purchased some binary liquid hydrogen peroxide products (i.e., subject matter of the claimed invention) from Wayne Chemical Inc. and began cleaning the plant. Once the plant was properly cleaned with Wayne Chemical Inc.'s hydrogen peroxide products, the USDA allowed them to start up again.

9. United Food Group placed a second order on or about 6/5/10. They, however, subsequently returned to using chlorinated cleaners and once again, *Listeria monocytogenes* appeared and they, again, called Wayne Chemical Inc. to purchase more of our binary liquid hydrogen peroxide products. They have been ordering from Wayne Chemical Inc. ever since and they have not had any recurrence of *Listeria monocytogenes*.

10. Chlorinated cleaners are less expensive than the products of the present application. But when there is a *listeria* outbreak often resulting in a very expensive recall and/or even causing the deaths of some consumers, cost no longer becomes an issue. The product of the present application kills more microorganisms than regular chlorinated cleaners evidenced by the fact that it is used on surfaces that are treated with chlorinated cleaners.

11. To further understand how cleaning food processing plants work it is important to understand the difference between cleaning and sanitizing. Those unskilled in this art may not appreciate the difference, but it is critical when it comes to keeping food processing plants safe.

12. Cleaning is the process of removing physical soils, such as food particles, organic soils, dirt, etc., from the machinery, flooring, walls, ceilings, and other surfaces at a food processing plant. Before anything can be sanitized, these soils must be removed. Sanitizers are not effective over soil loads. In other words, the surfaces must be cleaned before sanitizing begins. As previously discussed, chlorinated cleaners are the traditional cleaning product (prior to the introduction of the subject matter of this patent application) for performing this cleaning step.

13. Water is used in combination with these binary cleaners to lift and rinse the particles and organic soils from the surfaces of the machinery, flooring, walls and ceilings in the food processing plant.

14. Sanitizing, in contrast to cleaning, kills the microorganisms that may still remain after cleaning. To do this, however, requires the food soils to already be removed, thereby

exposing the entire surface to the sanitizer. That is why there is a two step process. Cleaning and sanitizing at the same time does not satisfactorily remove all of the food soils from a surface and simultaneously sanitize underneath. And as previously discussed, the FDA and USDA forbids this combined approach.

15. The liquid composition of the cleaner and associated method described in this present patent application is distinctly used for the cleaning step, not the sanitizing step. I have found that by mechanically cleaning (i.e., removing organic soils and particles from surfaces) in a food processing plant using my invention followed by the conventional sanitizing step, reduced the microbial count more significantly than by cleaning with the chlorinated cleaner followed by the same sanitizing step.

16. The Examiner contends that a previous declaration containing a compilation of research articles showing the corrosive nature of bleach was not persuasive because it merely showed bleach was corrosive. But that is the problem with chlorinated products, they are corrosive. The claimed invention is a non-corrosive formulation so it cannot, therefore, include bleach or bleach activators. As discussed in my Declaration dated October 25, 2007 at paragraph 7, bleach activators react with peroxides in alkaline conditions to generate peracids and potent oxidants creating a bleaching species. This can promote corrosion which is expressly excluded from the claim. In other words, our composition accomplishes better cleaning and no corrosion by omitting corrosive constituents. The claimed invention raises the pH so any of these activators will generate peracids, which are corrosive and thus cannot be part of the claimed invention.

17. The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Declared at Fort Wayne, Indiana, this 21 day of April, 2010.

W E Spindler

William E. Spindler

State of Indiana)

) ss:

County of Allen)

On this 21st day of APRIL, 2010, before me, a Notary Public in and for the County and State aforesaid, appeared William E. Spindler, to me personally known to be the same person whose name is subscribed to the foregoing instrument, and acknowledged that he executed said instrument as his free and voluntary act and for the uses and purposes therein expressed.

[Signature]

Notary Public

TOOP A ELLIS

Printed Name

My Commission Expires: APRIL 7, 2017

County of Residence: ALLEN